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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,391	07/07/2000	JEROEN KRIJGSVELD	702-000648	1936

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/509,391

Applicant(s)

KRIJGSVELD ET AL.

Examin r

Sheridan K Snedden

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-40,49 and 51-61 is/are pending in the application.
- 4a) Of the above claim(s) 39,41-47 and 58-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 36-38,40,49 and 51-57 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. This Office Action is in response to Paper #20, filed 15 January 2003. Applicant's amendment of claim 36 is acknowledged. Claims 1-35, 48 and 50 are cancelled. Claims 39, 41-47, and 58-61 have been withdrawn from consideration. Claims 36-38, 40, 49, 51-57 are under examination.
2. Applicant's traverse the restriction imposed on claims 39 and 41-47 and argue that the claimed sequences are similar in structure and function. Additionally, applicant argues that claim 36 provides the requisite scope for the methods of claims 58-61. These arguments have been considered but are not persuasive. Of the current pending claims, there are no allowable generic or linking claims to support a rejoinder of the withdrawn claims and sequences. The peptides differ in structure and do not share a common sequence and are thus, patentably distinct. As a different search is required for each patentably distinct peptide, restriction for examination purpose is proper.

Withdrawal of Objections and Rejections

3. The objections and/or rejections not explicitly restated or stated below are withdrawn.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 36-38, 40 and 52-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Daly *et al.* (Patent No: 5,656,724). Daly *et al.* disclose recombinant CXC chemokines whose amino acid sequences, SEQ ID NO: 9 and 10, comprise the exact same amino acid sequence of TC-1, SEQ ID NO: 12, and TC-2, SEQ ID NO: 6 (claims 36-38, 40 and 52-55; note that the optional modifications recited in claim 36 are not considered). In addition, Daly *et al.*, column 1 line 32, disclose these CXC chemokines as small inducible proteins having a specific arrangement of four position-invariant cysteine residues in their primary amino acid sequence that form two disulfide bonds. Thus, the reference anticipates the claimed invention.

Applicant has amended claim 36 to substitute the phrase "consisting essentially of" for "comprising" and contends that this amendment overcomes the cited art. This argument is considered but not persuasive. The claimed peptide of TC-1 (SEQ ID NO: 12) differ from that of the reference by the presence of 10 additional amino acids at the N-terminal. The claimed peptide of TC-2 (SEQ ID NO: 6) differ from that of the reference by the presence of 1 additional amino acids at the C-terminal. Otherwise, the reference discloses recombinant CXC chemokines whose amino acid sequences comprise the entire, identical amino acid sequence of TC-1, SEQ ID NO: 12, and TC-2, SEQ ID NO: 6. The absence of the 10 and 1 amino acids from the peptides of the references would not materially affect the antimicrobial action of the CXC chemokines, and thus read on the claims. As such, the language "consisting essentially of" would possess the same meaning as "comprising" when read into the claim. The peptides of Daly *et al.* are essentially identical to the amino acids of the claimed peptides, comprise the full sequences of SEQ ID NO: 12 and 6, and possess the expected antimicrobial activity of the claimed peptides.

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6. Claims 36, 38, 49, 51-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Baggiolini *et al.* (WO 90/06321). Baggiolini *et al.* teach the administration of daily doses (claim 33) of recombinant CXC chemokine NAP-2 for the treatment of human conditions associated with bacterial and fungal infections (page 9 third paragraph; regarding claims 48-51 and 56). Comparison of the sequences given in figure 1 of the specification show that NAP-2 is 97% identical to TC-1 (SEQ ID NO: 12; regarding claims 52-55). The sequence of NAP-2 differs from the sequence of TC-1 by the presence of 2 additional amino acids on the N-terminus, thus, the sequence of NAP-2 fully comprises the sequence of TC-1, or SEQ ID NO: 12 (regarding claims 36 and 38). Thus, the reference anticipates the claimed invention.

Applicant has amended claim 36 to substitute the phrase "consisting essentially of" for "comprising" and contends that this amendment overcomes the cited art. This argument is considered but not persuasive. The claimed peptide of TC-1 (SEQ ID NO: 12) differ from that of the reference by the presence of 2 additional amino acids at the N-terminal. Otherwise, the reference discloses NAP-2 whose amino acid sequences comprise the entire, identical amino acid sequence of TC-1, SEQ ID NO: 12. The absence of the 2 amino acids in the claimed peptide would not materially affect the antimicrobial action of NAP-2, and thus read on the claims. As such, the language "consisting essentially of" would possess the same meaning as "comprising" when read into the claim. The peptides of Baggiolini *et al.* are essentially identical to the claimed peptides, comprise the full sequences of SEQ ID NO: 12, and possess the expected antimicrobial activity of the claimed peptides.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 36, 38, and 48-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baggiolini *et al.* (WO 90/06321) in view of Cimbollek *et al.* (1996).

Baggiolini *et al.* teach the administration of daily doses of recombinant CXC chemokine NAP-2 for the treatment of human conditions associated with bacterial and fungal infections (pages 9-10; regarding claims 48-51 and 56). Comparison of the sequences given in figure 1 of the specification show that NAP-2 is 97% identical to TC-1 (SEQ ID NO: 12; regarding claims 52-55). The sequence of NAP-2 differs from the sequence of TC-1 by the presence of 2 additional amino acids on the N-terminus, thus, the sequence of NAP-2 fully comprises the sequence of TC-1, or SEQ ID NO: 12 (regarding claims 36 and 38). Baggiolini *et al.* does not disclose the NAP-2 for the treatment of bacterial and fungal endocarditis.

Cimbollek *et al.* teach that both fungal and bacterial infections are associated with endocarditis (page 1432, first paragraph; regarding claim 57).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the known antimicrobial chemokine, NAP-2, for the treatment of endocarditis caused by fungal and bacterial infection. The person of ordinary skill in the art would have been motivated to treat endocarditis with the above chemokine because the chemokine has known antimicrobial activity. The person of ordinary skill in the art would have

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expected success because endocarditis is caused by both fungal (claim 34) and bacterial (claim 32) infections (Cimbollek *et al.*). Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

9. Applicant argues that the absence of residues in TC-1 result in differences in the structure and activity of the peptide as compared to the sequences taught by Baggiolini *et al.* This is not found persuasive because the references teach a peptide NAP-2, which consist essentially of the claimed sequence of SEQ ID NO: 12. The claimed peptide of TC-1 (SEQ ID NO: 12) differ from that of the reference by the presence of 2 additional amino acids at the N-terminal. Otherwise, the reference discloses NAP-2 whose amino acid sequences comprise the entire, identical amino acid sequence of TC-1, SEQ ID NO: 12. The absence of the 2 amino acids in the claimed peptide would not materially affect the antimicrobial action of NAP-2, and thus read on the claims. As such, the language "consisting essentially of" would possess the same meaning as "comprising" when read into the claim. The peptides of Baggiolini *et al.* are essentially identical to the claimed peptides, comprise the full sequences of SEQ ID NO: 12, and possess the expected antimicrobial activity of the claimed peptides.

Conclusion

10. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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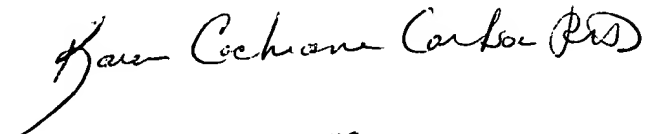
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
November 5, 2003
SKS


KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER